

REMARKS

Claims 1, 6, and 7 now stand rejected under 35 U.S.C. 103(a) as being obvious over Wong et al. (U.S. Patent No. 5,492,904) in view of Sjoerdsma (U.S. Patent No. 4,189,492).

Applicant refers the Examiner to the prior response which is hereby incorporated by reference and wherein a summary of Wong, United States Patent 5,492,904, is set out and to which the Examiner is referred.

Applicant's invention utilizes fosinopril sodium in combination with the lubricant zinc stearate having the unexpected result of also effecting tablet degradation. The products of degradation are clearly set out in Applicant's disclosure at column 2 of the published application. It has therefore been clearly determined by the Applicant and established by experimentation that zinc stearate when present as a lubricant in the tablet also had the unexpected advantage of minimizing degradation products when compared to the other well known lubricants, such as those listed.

It is clear from Wong that he had no understanding of the advantages of choosing a lubricant with the minimum of degradation by products such as zinc stearate, taught and claimed in the present application. This is clearly evidenced by the fact that in Wong's examples he did not appreciate the advantages and benefits of using zinc stearate as a lubricant since in formulating his capsules and tablets he elected to use magnesium stearate assuming that it would function as well as any of the other known lubricants. It is clear therefore that Wong did not understand the advantages of utilizing zinc stearate as a lubricant in his formulation since he did not appreciate the benefits resulting from using same over other well known lubricants.

Even though Wong may in fact at one remote location in his teaching refer to fosinopril sodium and lactose he only did so in context of his invention which is a composition including two components, one being the angiotensin II antagonist and the other being the calcium channel blocker. Fosinopril was stated only as one alternative in a list of many possible antihypertensives to be added to the combination. At no time however did Wong state that he appreciated that the lubricant zinc stearate could also be used to reduce the degradation products of his composition. There is no discussion of this issue whatsoever in Wong. Clearly, this being the case Wong lacks this understanding and teaching now present in Applicant's claims as amended

Referring now to Sjoerdsma (U.S. Patent No. 4,189,492) hereinafter referred to as '492, there is taught a therapeutic antihypertensive composition for reducing blood pressure in mammals. Particularly his invention relates to novel therapeutic compositions of lofexidine. A review by Applicant of the specification results in a conclusion that fosinopril sodium is not discussed whatsoever in the specification of the '492 reference. The Examiner has stated that it would be obvious to combine the teachings of Wong with the '492 reference. Zinc stearate is not taught in Wong as admitted by the Examiner who has, therefore, relied on the teachings of the '492 reference as motivation for any alleged combination.

Clearly Wong had available to him the teachings of the '492 reference and did not choose to identify zinc stearate as a lubricant. Even if one were to combine the teachings of Wong and the '492 reference it is clear from the examples of the '492 reference that Sjoerdsma clearly had no understanding of the advantages of utilizing one lubricant over the other and particularly zinc stearate. This is evidenced by the fact that in examples 1 and 2 the inventor chose to use calcium stearate as a lubricant, which is identified in Applicant's teachings

clearly as one of the worst possible choices that he could have made namely calcium stearate as a lubricant in terms of the generation of degradation products set out on page 4 of Applicant's disclosure.

The traditional test enunciated in Graham vs. John Deere Company 383 U.S. 1, 148 U.S.P.Q. 459 1966, for Section 103 nonobviousness requires the fact finder to make several determinations. The test provides that the scope and content of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and the level of ordinary skill in the pertinent art be resolved. Thus, the patentability of the claims at hand must stem from the fact that the specific combination of the claimed elements was not disclosed in the prior art and the additional allegation that the specific combination of claimed elements was nonobvious to one of ordinary skill in the art.

Clearly, the prior art does not suggest or provide any reason or motivation to make such a modification as purported by the Examiner. With reference to In Re: Regal, 526 F. 2d 1399, 1403 n. 6, 188 USPQ 136, 139 n. 6 (CCPA 1975).

*"There must be some logical reason apparent from positive, concrete evidence of record which justifies a combination of primary and secondary references".*

In Re: Geiger, 815 F. 2d 686, 688, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (obviousness can not be established by combining pieces of prior art absence some "teachings, suggestion, or incentive supporting the combination"): In Re: Cho. 813 F. 2d 378, 382, 1 USPQ 2d 1662, 1664 (Fed. Cir. 1987)("discussing the Board's holding that the artisan would have been motivated to combine the references").

Therefore, it Applicant's view there is no evidence of motivation in the prior art, either within the references themselves, or knowledge generally available to one of ordinary skill in the art, to make the purported changes suggested by the Examiner to arrive at the claimed subject matter.

Therefore clearly neither Wong nor Sjoerdsma understood the problem solved by Applicant's amended claim 1, that is the use of zinc stearate as a lubricant present also to limit the amount of degradation products for the tablet in comparison to other known lubricants such as magnesium stearate, and calcium stearate.

How then can any combination proposed by the Examiner of Wong and the '492 reference result in Applicant's invention as set out in his amended claim set, if neither Wong nor the '492 reference appreciated the problem? The motivation in the art is clearly lacking.

As evidence of this fact Applicant encloses with this submission the Declaration of Dr. Michael Lipp, the contents of which being hereby incorporated by reference in their entirety into this amendment as if they had been included herein in their entirety. The Examiner is referred to Dr. Lipp's Declaration as evidence of the arguments presented herein. Dr. Lipp concludes in paragraph 53 of his Declaration:

*As a result, I disagree with the Examiner with respect to the Examiner's allegation that a skilled formulator would have utilized zinc stearate as taught by the '492 patent (Sjoerdsma) as the lubricant in the formulations disclosed in the '904 patent (Wong) in order to improve stability and optimize the delivery of fosinopril sodium. Again, I do not see any motivation for a skilled formulator to combine the teachings of the '904 and '492 patents in the manner alleged by the Examiner. In my opinion, neither the '904 patent nor the '492 patent, nor the*

*combination thereof teach any information concerning the nature of the problem solved by the invention of the '352 patent application, namely the use of zinc stearate as a lubricant to provide for the production of tablets containing fosinopril sodium with superior stability. Further, the disclosures of the '904 and '492 patents give no indication that the inventors thereof had any understanding of the nature of the problem solved by the invention of the '352 patent application.*

The Examiner is referred to the details of the Declaration which substantiate this conclusion!

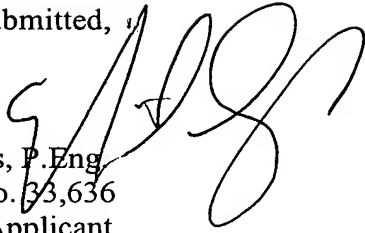
Applicant and Dr. Lipp by way of expert evidence therefore have assessed the prior art cited by the Examiner and have made amendments to overcome his alleged prior art rejections as well as providing expert evidence and arguments with regard to the inappropriateness of the Examiner's remarks in misreading of the prior art and attempting to create an improper 20/20 hindsight reconstruction. Applicant has also fully refuted the Examiner's combination of the prior art and set out according to the accepted principles of *Graham v John Deere* cited above and identified the differences in the claims as amended that distinguish over the prior art cited by the Examiner and the lack of motivation in the art nor expectation of success required by the courts in his attempt to create an improper hindsight reconstruction. Full reconsideration is respectfully requested.

If any other fees should be determined to be required by the Examiner he is requested to access Applicant's Agent's Deposit Account No. 08-3255 for this purpose and advise Applicant's Agent accordingly.

If the Examiner has any questions, he is requested to contact Neil H. Hughes at (905) 771-6414 at his convenience.

Respectfully submitted,

Neil H. Hughes, P.Eng  
Registration No. 33,636  
Agent for the Applicant

A handwritten signature in black ink, appearing to read 'N. Hughes', written over the printed name and registration number.

NHH:hp  
Enclosures